REMARKS

This is a response to the Office Action dated January 15, 2004. Claims 1-34 are pending in this application. Claims 1-8 have been rejected by the Examiner, and Claims 9-18 have been withdrawn. As noted above, Applicant has amended Claims 1 and 5, and has submitted New Claims 19-34. The amendments and the New Claims 19-34 are fully supported by the written description. No new matter has been introduced into the application.

Claim Rejections - 35 USC § 102

Claims 1-8 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Berg et al. (U.S. Patent Number 5,464,650). Berg et al. is directed to a method of coating a stent with a solution having a polymer and a solvent. The methods disclosed by Berg et al. are completely contrary to the teachings of the present invention. In fact, as the Specification clearly indicates, the present invention is meant to solve the problems created by the conventional coating methods described in Berg et al.

Berg et al. discloses a method of forming a coating on a stent by applying "a solution which includes a solvent, a polymer dissolved in the solvent and a therapeutic substance dispersed in the solvent and then evaporating the solvent." Column 2, lines 33-36. Although Berg et al. discloses that the coating can be formed by varying the ratio of drug to polymer in multiple layers (see Column 2, lines 61-64), Berg et al. clearly indicates that the coating must be **dried in between each coating step**. In particular, Berg et al. specifically discloses that, "[t]he amount of drug to be included on the stent can be readily controlled by applying multiple thin coats of the solution **while allowing it to dry between coats**." Column 2, lines 44-47 (emphasis added).

On the other hand, the present invention (e.g., as claimed in Claim 1) is directed to a method of coating a stent by modifying a ratio of a first ingredient with respect to a second ingredient **while the ingredients are being applied to the stent**. Berg et al. clearly fails to

disclose this step of modifying the ratio as the composition is being applied to the stent. In particular, with reference to Claim 1, Berg et al. fails to disclose a method of forming a coating on a stent, comprising:

> applying a coating formulation to a stent, the coating formulation including a first ingredient and a second ingredient; and
>
> **modifying the ratio of the first ingredient with respect to the second ingredient in the coating formulation <u>as the coating formulation is being applied to the stent</u>.**

As noted above, Berg et al. merely discloses a conventional coating technique in which multiple layers of a coating substance are formed by independent application steps. Each application step is separated by a drying step in which the solvent is allowed to dissipate. The conventional approaches described in Berg et al. are associated with several disadvantages that the present invention is meant to address. The Specification on page 2 outlines some of the disadvantages of the conventional approaches:

> some conventional techniques apply a coating to a stent that has more than one layer, with each layer having a different composition. These techniques also suffer from some flaws. For example, the different layers may not strongly adhere to each, thereby allowing one or more layer to leach into the blood or become detached creating an embolization hazard. Also, the coating process of these techniques may not be very efficient because each layer must be applied, and then dried before the next layer is applied.

As the Specification suggests, the Berg et al. coating process may form a coating that has different layers that do not adhere well to each other, and may not be a very efficient process because each layer must be applied and then dried before applying the next layer. See Column 2, lines 44-47.

Moreover another goal of the present invention is to produce a coating that does not have a high early dose (i.e., a "burst-effect"):

> Finally, the application of the composition for each additional layer subsequent to the drying of the previously applied layer can cause the extraction of the drug out of the previous layer. Accordingly, the concentration of the drug will reside in the upper most layers, causing a rapid release of the drug subsequent to the implantation procedure. This

> "burst-effect" leads to a reduced residence time of the drug at the implantation site, which may be undesirable depending on the type of condition being treated.

Berg et al. admit that their technique can produce a coating having a high early dose: "[t]he release rate can be further controlled by varying the ratio of drug to polymer in the multiple layers. For example, a higher drug-to-polymer ratio in the outer layers than in the inner layers would result in **a higher early dose** which would decrease over time." Column 2, lines 63-67 (emphasis added).

It should also be noted that Berg et al. fails to disclose all of the limitations of the dependent claims. For instance, Berg et al. does not disclose a method of applying a coating formulation where, "the ratio is modified by **gradually increasing the concentration of the first ingredient in the coating formulation from the initiation of the application of the coating formulation to the stent until the termination of the application of the coating formulation to the stent**" as recited by Claim 8.

In short, Berg et al. merely discloses some of the conventional coating techniques that the present invention is meant to address. Therefore, the Claims as presently presented are allowable over Berg et al.

CONCLUSION

Claims 1-34 are pending in the application. Examination and allowance of the claims are respectfully requested.

If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned attorney at (415) 954-0345.

Date: April 16, 2004

Respectfully submitted,

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